

44

DM



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,405	07/30/2001	Jochen Heinz	5083-25	4667

7590 01/17/2002

COHEN, PONTANI, LIBERMAN & PAVANE
551 Fifth Avenue, Suite 1210
New York, NY 10176

EXAMINER

ASSADI, KATHRYN L

ART UNIT PAPER NUMBER

3763

DATE MAILED: 01/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/918,405	Applicant(s) HEINZ ET AL.	
Examiner Kathryn L Assadi	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 July 2001.
- 2a) This action is FINAL.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) 13 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 30 July 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) Interview Summary (PTO-413) Paper No(s). _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other:

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the lubricious plastic of the longitudinally displaceable plunger part connected to the plunger rod must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The specification is rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. The specification discloses a sliding layer on the outer circumference of the plunger rod that is of silicon. However, silicon does not inherently possess the properties that are discussed in the disclosure.

Claim Objections

Claim 13 is objected to because of the following informalities: Examiner makes note that Claim 13 should read "A metering receptacle according to claim 1, wherein the plunger rod has a bleeding channel parallel to a longitudinal axis of the plunger rod,"

Art Unit: 3763

instead of "...wherein the plunger rod is a bleeding channel..." Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szwarc (US 4,613,326). Szwarc discloses a metering receptacle comprising an elongate hollow body (Figure 5, 21) having a first end with a closable exit opening and a second end. A flexible plunger stopper (36) is shown that is accommodated in the hollow body in a longitudinally displaceable manner so as to close the second end of the hollow body. Szwarc also discloses that the plunger stopper has a centric bore for the passage of the plunger rod (37) and that the plunger part is formed as one piece with the plunger rod (37). Even though Szwarc does not specifically disclose that the plunger stopper or plunger part connected to the plunger rod is plastic, it would be obvious to one with ordinary skill in the art that the flexible stopper Szwarc discloses could be made of plastic, since plastic is a flexible substance. Also it would be obvious that in order for the stopper to move along the barrel, it should be well lubricated (See Column 8, lines 15-35). Thus, making it obvious that the plunger stopper including a

Art Unit: 3763

sealing stopper part of plastic and a plunger part of lubricious plastic connected to the plunger rod would allow for the stopper's ability to slide through the barrel.

Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szwarc in view of Sams (US 5,743,889). Szwarc teaches all of the limitations of the claims except for disclosing a metering receptacle wherein the plunger part is releasably connected to the plunger rod by a screw connection. Sams discloses a syringe similar to the syringe of Szwarc wherein the plunger part is releasably connected to the plunger part by a screw connection (Abstract). It would be obvious to one with ordinary skill in the art to modify the syringe of Szwarc by connecting the plunger part to the plunger rod by a means such as a screw connection in order to disassembly the metering receptacle for purposes of cleaning it.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szwarc in view of Thibault et al (US 5,607,400). Szwarc teaches all of the limitations of the claims except for applying a low friction material on the stopper. Thibault et al discloses that to facilitate sliding, a low friction material may be disposed on the stopper (Column 2, lines 60-62). It would be obvious to one with ordinary skill in the art that the low friction material that Thibault teaches can be a sliding layer that can be applied on the outer circumference of the plunger rod, since a layer that slides has low friction. It would also be obvious to one with ordinary skill in the art to use a plunger rod made of a self-lubricating plastic to facilitate sliding of the barrel along the interior of the hollow body since plastic that is self-lubricating slides easier than plastic that is not self-lubricating.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Szwarc in view of Thibault as applied to claims 5-7 above, and further in view of Kolberg (US 6,053,895). Szwarc and Thibault teach all of the limitations of the claim except for a plug made of polytetrafluoroethylene (PTFE). Kolberg discloses a plug made of PTFE (See Abstract). It would be obvious to one with ordinary skill in the art to use a rod made of PTFE since as Kolberg teaches, PTFE displays good sliding properties that would allow for the rod to slide through the hollow body easily.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Szwarc in view of Thijs et al (US 5,163,919). Szwarc teaches all of the limitations of the claim except for a stopper part of elastomeric plastic. Thijs et al discloses a stopper part of an elastomer plastic (Column 4, lines 2-5). It would be obvious to one with ordinary skill in the art to use an elastomer plastic because it is one of the various types of stoppers that can be used in a metering receptacle.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szwarc in view of Kolberg et al (US 6,053,895). Szwarc teaches all of the limitations of the claims except for sealing lips on the outer circumference and centric bore of the stopper part as well as circumferential sealing lips on the plunger part. Kolberg teaches of a stopper that has at least one sealing lip on its outer circumference which seals against the inside wall of the barrel. It would be obvious to one with ordinary skill in the art to make a stopper part not only with sealing lips on the outer circumference but in the centric bore as well, in order to secure the plunger rod. Likewise, in view of

Art Unit: 3763

Kolberg's teaching, for secure sealing purposes, it would be obvious to make a plunger part with circumferential sealing lips on a side proximal to the stopper part.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Szwarc in view of Hecker. Szwarc teaches all of the limitations of the claim except for a bleeding channel parallel to a longitudinal axis of the plunger rod. Hecker discloses a channel (22) that extends along a longitudinal axis through the needle guide platform. Even though the channel that Hecker discloses is used to dispose a needle which is axially movable along an axis of injection through the channel, it would be obvious to one with ordinary skill in the art that a channel parallel to a longitudinal axis of the plunger rod could also be used as a means through which air may flow from the outside into the space between the plunger part and the rigidly positioned stopper part, so as to prevent the formation of a vacuum in the above-mentioned space.

Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szwarc over Thibault. Thibault discloses a prefilled syringe (Column 2, line 33). It would be obvious to one with ordinary skill in the art that a prefilled syringe is a prefilled receptacle. Also, it is obvious to one with ordinary skill in the art that a syringe is disposable because for sanitation purposes a syringe should not be used more than once.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn L Assadi whose telephone number is 703-305-3286. The examiner can normally be reached on 8:30 AM - 6:00 PM: 1st Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

KLA
January 14, 2002


Brian L. Casler
Primary Examiner

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a)

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.